

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 16, 2002, from 10:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12522. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a draft guidance entitled “Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA.” The topics for discussion will include the appropriate study population, objective measurement techniques for comparison of acoustic hearing aids and middle ear hearing devices, and subjective questionnaire development for determining postoperative effectiveness and quality of life outcome measures. The draft guidance is available to the public on the Internet at <http://www.fda.gov/cdrh/ode/guidance/1406.html>.

Background information, including the attendee list, agenda, and questions for the committee, will be available to the public on August 15, 2002, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: On August 16, 2002, from 12:30 p.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 8, 2002. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 1:10 p.m. and 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 8, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations. On August 16, 2002, from 10:30 a.m. to 12:30 p.m., the meeting will be closed to the public to permit discussion and

3

review of trade secret and/or confidential information regarding pending issues and applications (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 111111111111

11111111111111111111

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S